

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION**

MARCUS H. TALLEY,

Plaintiff,

vs.

EXACTECH, INC. and
EXACTECH US, Inc.,

Defendants.

CASE NO. _____

**COMPLAINT
AND JURY DEMAND**

COMPLAINT AND JURY DEMAND

COMES NOW the Plaintiff, MARCUS H. TALLEY, by and through undersigned counsel and submits this Complaint and Jury Demand against Exactech, Inc. (“Exactech”) and Exactech US, Inc. (“Exactech US”)(collectively “Defendants”) for compensatory and punitive damages equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff Marcus H. Talley suffered as a direct and proximate result of Defendants’ designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting and/or selling the defective device sold under the name “Optetrak” total knee replacement system (hereinafter “Optetrak” or “Defective Device”). In support, Plaintiff alleges the following:

INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants, and/or employees designed, developed, tested, assembled, manufactured, packaged, labeled, prepared,

distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a total knee replacement.

2. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks from Plaintiff, including an increased risk of failure in overweight and obese patients, Plaintiff's medical providers, other consumers, and the medical community at large.

3. As a result of the defective nature of the Optetrak knee replacement procedure, persons who were implanted with a Defective Device, including Plaintiff, have suffered, and may continue to suffer, severe and permanent personal injuries, including painful knee revision surgery to remove or revise the Defective Device, continued rehabilitation, medical care, and possible additional surgeries.

4. After being implanted with the Defective Device, Plaintiff experienced pain and other symptoms, and as a direct and proximate result of the Defendants' actions and inaction, Plaintiff required a revision surgery to remove the Defective Device. The Optetrak knee replacement implant was defective, unreasonably dangerous, and caused permanent injury and damages to Plaintiff.

5. This is a product liability action for failure to warn, negligence, fraud, misrepresentation, breach of warranties, and violation of Alabama's Deceptive Trade Practices Act against Defendants.

6. Plaintiff brings this action for personal injuries suffered as a proximate result of being implanted with the Defective Device. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies provided to Plaintiff

under equity and law as a result of injuries caused by the implantation of the Defective Device and for Defendants' conduct.

PARTIES

7. At all times relevant hereto, Plaintiff Marcus H. Talley was a resident and citizen of Attalla, Etowah County, Alabama. As a result of the implantation of the Defective Device, Plaintiff suffered personal and economic injuries and sought treatment for the effects of the injuries that were the direct and proximate result of the implantation of the Defective Device and Defendants' conduct.

8. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopaedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally"¹ and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities,.

9. Exactech US, Inc., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Defendant Exactech Inc.'s "U.S. sales and distribution activities are conducted by [its] wholly owned subsidiary Exactech US, Inc."² and Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Defective Device, into interstate commerce, either directly or indirectly

¹ Exactech 2015 Form 10-k, p. 2. <https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1>

² *Id.*

through third parties or related entities. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as “Exactech” or “Defendants.”

JURISDICTION AND VENUE

10. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds \$75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

11. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Defective Device, within the State of Alabama with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

12. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to health care professionals in the State of Alabama, including Plaintiff’s health care professionals, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Alabama.

13. Defendants engaged in substantial business activities in the State of Alabama. At all relevant times, Defendants transacted, solicited, and conducted business in Alabama through

their employees, agents, and/or sales representatives and derived substantial revenue from such business in Alabama. Said activities including for the promotion, sale, and use of the Defective Device.

14. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Alabama. As such, this Court has personal jurisdiction over all named defendants.

15. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

16. At all times material hereto, Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device under various versions of the name “Optetrak.”

17. Upon information and belief the first Optetrak knee device was implanted in 1994.

18. Since 1994, Defendants have obtained 510(k) clearance for various Optetrak devices and tibial inserts including the Optetrak PS, Optetrak Hi-Flex PS, Optetrak Finned Tibial Tray, Optetrak Offset Tibial Tray, Optetrak RBK Tibial Insert, Optetrak RBK Tibial Tray, Optetrak CR Slope, and Optetrak Logic.

19. A typical knee replacement surgery, referred to as a total knee arthroplasty (“TKA”), is performed under general anesthesia. The primary indication for TKA is to relieve severe pain associated with arthritis and may also be used to correct knee trauma or minor knee deformities.

20. During the TKA procedure, the surgeon will make an approximately 8-10 centimeter incision on the front of the leg over the knee.

21. The surgeon will then prepare the femur portion of the knee, the distal femur. This process includes removing any diseased bone and drilling a hole in the femur in which to implant the femoral component of the device. The surgeon will then place a femoral implant onto the distal femur using surgical cement.

22. Next, the surgeon will prepare the proximal tibia, the bone located at the bottom of the knee. The tibial preparation includes, removing diseased bone, properly aligning the tibial tray, and drilling a hole in which to implant the tibial tray. The tibial tray is then implanted using surgical cement.

23. A third product, the tibial insert, is a polyethylene product implanted between the femoral implant and tibial tray.

24. Defendants promoted their Optetrak devices as a system with three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

25. The allegations in this Complaint relate to the early failure of the Defective Device and its tibial tray.

26. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold Optetrak tibial trays with a design Defendants referred to as “finned.”

27. By at least April 2008, Defendants became aware of a high rate of early failures with the “finned” Optetrak products.

28. Defendants were aware that early failures of the Optetrak knee implants required recipients of the Optetrak knee implant to undergo revision surgeries to remove the defective device.

29. By at least April 2008, Defendants were internally discussing the cause of early onset Optetrak knee implant failures.

30. By April 2008, Defendants, including company engineers, Optetrak design team contributors, and other employees were actively evaluating data related to early onset failure rates.

31. By April 2008, Defendants were designing a new tibial tray to replace the Defective Device.

32. Despite actual knowledge of the increased risk of failure related to the defective nature of the Optetrak knee implant design, Defendants made the decision not to recall, stop selling, or otherwise change the warnings for the affected devices until there was a suitable replacement approved for the U.S. market.

33. One potential failure mode recognized by Defendants by April 2008 was an increased failure rate in overweight and obese patients.

34. Data associated with early failures was presented to Defendants' Board of Directors by April 2008.

35. Despite Defendants knowledge of early onset failures of the Optetrak knee implants, Defendants continued to manufacture, promote, and distribute the Optetrak knee implants without alerting surgeons of potential increased risks posed to overweight and/or obese patients.

36. Despite Defendants knowledge of early onset failures of the Optetrak knee implants, Defendants continued to manufacture, promote, and distribute the Optetrak knee implants without changing, modifying or improving the Defective Device to address the increased risk posed to overweight and obese patients.

37. Despite Defendants knowledge of early onset failures of the Optetrak knee implants and the increased risk of failure for overweight and obese patients, Defendants never changed the labeling, marketing materials or product inserts to warn patients or physicians of the associated increased risks.

38. Despite Defendants knowledge of early onset failures of the Optetrak knee implants and the increased risk of failure for overweight and obese patients, Defendants never alerted the FDA of the known increased risks.

39. By 2012, Defendants had further clinical evidence that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to “loose tibial component”, “aseptic loosening”, “pain and visible loosening”, and “pain, limited mobility, knee swelling and sensitivity” due to “loose” joint. These early onset failure mode reports are representative of the increased rate of incidents of which Defendants had become internally aware.

40. In 2013 complaints continued to be reported. Examples of just some of the complaints made include revision for “tibial loosening” just two years postoperatively, “revision due to tibial loosening”, “during revision, the tibial component was found to be loose and easily removed”, “revision of knee component due to loosening”, “revision due to pain and loosening.”

41. The complaints of early onset failures continued in 2014. Some examples include “revision due to tibial loosening”, revision of “finned tibial tray due to tibial loosening”, “tibial

loosening”, “revision of optetrak knee components due to tibial loosening”, “revision due to pain and loosening”, “revision of optetrak knee components due to aseptic loosening”, several reports described as “revision of knee components due to tibial loosening”, and “revision of optetrak knee components reportedly due [to] aseptic loosening”

42. Upon information and belief, instead of warning consumers and the medical community about the increased failure rates with its finned Optetrak devices, Defendants engaged in a “silent recall” campaign where it slowly replaced all finned tibial trays with a new, more substantial design, referred to as “fit” trays. Concurrent with this strategy of product replacement, Defendants also engaged in a campaign of misinformation where any incidents of early onset failure were blamed on surgeon specific factors instead of admitting to any issues with the finned product itself.

43. In the year 2015, Defendants did over \$241 million in sales across all product lines.³ Further, Defendants state in the 2015 Form 10-K, “to better meet the demand for revision surgeries, we began the initial launch of a new revision knee system in 2015.”⁴

44. Of the more than \$241 million in sales, knee device sales accounted for over \$70 million in sales, or 29.3% of all Defendants’ sales in 2015.⁵

45. In 2016, Defendants’ revenue increased by 7%, up to \$257.6 million with knee device sales increasing 4%.⁶ Knee device sales for the fourth quarter of 2016 was accounted for \$19.8 million of this amount.⁷

³ See Exactech, Inc. Form 10-K for the fiscal year ended December 31, 2015, <https://www.exac.com/resource-library/investors/recent-filings/10-k-annual-report-1>

⁴ *Id.* at p. 4.

⁵ *Id.*

⁶ See Exactech, Inc. Form 8-K dated February 21, 2017, <https://www.exac.com/resource-library/investors/recent-filings/8-k-current-report-12>

⁷ *Id.*

46. According to Exactech CEO and President David Petty, the increases in knee device revenue “reflect excellent surgeon acceptance of Exactech innovations, including our three new revision systems.” Mr. Petty further stated that he anticipates the “revision knee rollout in the fourth quarter” of 2016 will “carry momentum into 2017.”⁸

47. A new knee implant, Truliant, is anticipated for release in the second half of 2017.⁹ Truliant received FDA 510(k) clearance, K170240, on February 23, 2017.

48. Despite Defendants’ claims in its promotional materials of over 30 years of successful outcomes with knee devices, Defendants knew of an unacceptably high early failure rate of its Optetrak knee implants.

PLAINTIFF SPECIFIC ALLEGATIONS

49. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device.

50. A defectively designed and manufactured Optetrak knee implant left the hands of Defendants in its defective condition. Defendants delivered the Defective Device into the stream of commerce and allowed it to be implanted in a total knee arthroplasty in Plaintiff.

51. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff required a knee revision surgery.

52. As a direct and proximate result of Defendants placing the Defective Device into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; past, present and future medical, hospital, rehabilitative and pharmaceutical expenses; and other related damages.

⁸ *Id.*

⁹ *Id.*

FEDERAL REQUIREMENTS

53. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

54. Pursuant to federal law, a device is deemed misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health if used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

55. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to a death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to a death or serious injury. Federal law also requires the FDA to establish regulations requiring a manufacturer of a medical device to promptly report to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation federal law which may present a risk to health. *See* 21 U.S.C. § 360i.

56. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to

assure that the device will be safe, effective and otherwise in compliance with federal law. *See* 21 U.S.C. §360j(f).

57. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq.* The Federal Register explains that the Current Good Manufacturing Practice (CGMP) regulations do not prescribe the details of how a manufacturer must produce a device because the regulations must apply to a variety of medical devices. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing process employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

58. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provisions in section 820 renders a device adulterated under section 501(h) of the Act. *See* 21 U.S.C. § 351.

59. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. “Quality system” means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR § 820.3(v).

60. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

61. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

62. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

63. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

64. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, batches, or their equivalents. Design validations shall ensure that the devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

65. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

66. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation.

67. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing

process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

68. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification method, process, or procedure.

69. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control systems to verify that the system, including necessary equipment, is adequate and functioning properly.

70. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or products by substances that could reasonably be expected to have an adverse impact on quality.

71. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

72. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality in order to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

73. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer is required to validate computer software for its intended use according to an established protocol.

74. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer must establish and maintain procedures to ensure that equipment is calibrated, inspected, checked, and maintained.

75. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspections and testing, the process shall be validated with a high degree of assurance and approved according to established procedures. “Process validation” means establishing, by objective evidence, that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

76. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring internal processes and establish control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified persons.

77. Pursuant to 21 CFR § 820.90, each manufacturer also must establish and maintain procedures to control products that do not conform to specified requirements.

78. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventative actions.

79. Based on information and belief, Defendants’ knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

80. Based on information and belief, Defendants' knee implant devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

81. Based on information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its knee implant devices in accordance with 21 CFR § 820 *et seq.*, as set forth above.

82. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing and process validation for its knee implant devices.

83. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' knee implant devices were defective and failed, resulting in injuries to Plaintiffs.

84. If Defendants had complied with the federal requirements regarding CGMP, Defendants' knee implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiffs.

FIRST CAUSE OF ACTION
NEGLIGENCE

85. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Defective Device into the stream of commerce, including a duty to

assure that their products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

87. Defendants had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

88. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

89. Plaintiff, as a purchaser of the Defective Device, is within the class of persons that the statutes and regulations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

90. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with the Defective Device.

91. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Defective Device.

92. Defendants breached their duty and failed to exercise ordinary care and/or were negligent and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance,

quality control, labeling, marketing, promotion and distribution of the Defective Device into interstate commerce because Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

93. Despite the fact that Defendants knew or should have known that the Defective Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Defective Device for implantation into consumers and/or continued to fail to comply with federal requirements.

94. The Defendants failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

- a. Failing to properly and thoroughly test the Defective Device before releasing the device to market;
 - b. Failing to properly and thoroughly analyze the data resulting from the premarketing tests of the Defective Device;
 - c. Failing to conduct sufficient post-market testing and surveillance of the Defective Device;
 - d. Designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Defective Device;
 - e. Failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Defective Device;
 - f. Failing to exercise due care when advertising and promoting Defective Device;
- and

- g. Negligently continuing to manufacture, market, advertise, and distribute the Defective Device after the Defendants knew or should have known of its adverse effects and/or the increased early onset failure rates.

95. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

96. As a direct and proximate result of Defendants' negligence and/or wantonness, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

97. Plaintiff contends that the conduct of the Defendants as described above, including, but not limited to, their failure to adequately design and manufacture, as well as their continued marketing and distribution of the Defective Device when they knew or should have known of the serious health risks the device created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life, which warrants the imposition of exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SECOND CAUSE OF ACTION
VIOLATION OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT

98. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

99. Defendants engaged in unfair and deceptive trade practices with Plaintiff in the following respects:

- a. Defendants are merchants, who study, test, design, develop, manufacture, inspect, produce, market, promote, advertise, distribute and/or sell medical devices, including the Defective Device;
- b. Defendants knowingly committed unfair and deceptive practices in their study, testing, design, development, manufacture, inspection, production, marketing, promotion, advertising, distribution, and/or sale of the Defective Device;
- c. Defendants knowingly committed unfair and deceptive practices when they failed to safely design and construct a safe and effective knee implant device for use by Plaintiff;
- d. While Defendants knew or reasonably should have known that the Defective Device, when used as intended caused a significantly increased risk of injuries, including painful knee revision surgery, while they were engaged in the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or selling the Defective Device, Defendants did not inform the FDA, Plaintiff, and/or Plaintiff's physicians of their knowledge concerning the dangers posed to patients;
- e. Defendants failed to give adequate warnings regarding the use and potential problems with the Defective Device;

- f. Defendant's actions occurred while they were engaged in trade and commerce, and all of the conduct occurred during the course of their business.

100. Defendant's conduct in continuing to market, sell, and distribute the Defective Device without proper warnings after obtaining knowledge that the Defective Device caused a significantly increased risk of injuries, including painful knee revision surgery, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

THIRD CAUSE OF ACTION
ALABAMA EXTENDED MAUFACTURERS' LIABILITY DOCTRINE
ALABAMA CODE §§ 6-5-501 *et seq.*

101. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

102. Defendants are strictly liable to Plaintiff under Ala. Code §§ 6-5-501 *et seq.* ("AEMLD").

103. Defendants have engaged in the business of designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, and/or distribution of the Defective Device. Through that conduct, Defendants knowingly and intentionally placed

the Defective Device into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff.

104. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released the Defective Device into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted the Defective Device to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks of high early failure rates associated with the implantation of the Defective Device.

105. Defendants expected the Defective Device to reach, and it did in fact reach, implanting orthopedic surgeons, health care professionals and consumers, including Plaintiff and Plaintiff's health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

106. The Defective Device, as manufactured and/or supplied by Defendants, was defective due to its high early failure rate. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

107. The Defective Device was defective and unsafe such that it was unreasonably dangerous when it left the Defendants' possession and/or control, was distributed by Defendants, and implanted by Plaintiff's surgeon.

108. The Defective Device design created an unreasonable risk of early failure and resulting painful revision surgery.

109. Defendants failed to warn or alert consumers, including Plaintiff, to the dangerous risks associated with the Defective Device, including the risk of early revision surgery.

110. This defect caused serious injury to Plaintiff, who used the Defective Device for its intended purpose and in a reasonably anticipated manner.

111. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as necessary to ensure the Defective Device did not cause users to suffer from unreasonable and dangerous risks.

112. Defendants negligently and recklessly designed, distributed, and promoted the Defective Device.

113. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the early failure of the Defective Device.

114. Defendants, as designers, manufacturers, sellers, and/or distributors of medical devices, are held to the knowledge of an expert in the field.

115. Plaintiff could not have discovered any defects in the Defective Device through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

116. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that the Defective Device caused serious injuries, including early revision, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its implantation. The dangerous propensities of the Defective Device, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they designed, distributed, supplied, or sold the Defective Device. Such information was not known to ordinary physicians who would be expected to implant the Defective Device.

117. The Defective Device, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably intended manner without knowledge of this risk of serious bodily harm.

118. Further each of the Defendants knew or should have known through post market surveillance and other methods that the Defective Device was inadequate and resulted in a high risk of early failure, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to implant the Defective Device.

119. In particular, Defendants failed to communicate the knowledge of high early failure rates that render the Defective Device unsafe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the Defective Device.

120. Defendants communicated to health care professionals information that failed to contain relevant notice of know high early failure rates that would enable health care professionals to implant safe and effective knee implant devices. In particular, Defendants:

- a. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Defective Device;
- b. Continued to aggressively promote the Defective Device even after Defendants knew or should have known of the unreasonable risks from implantation;
- c. Failed to provide information that accurately reflected the high early failure rate of the Defective Device; and
- d. Downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the implantation of the Defective Device.

121. To this day, Defendants have failed to adequately and accurately disclose the true risks of high early revision rates associated with implantation of the Defective Device.

122. Due to the deficiencies and inadequacies of the Defective Device, it was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

123. Had Defendants properly disclosed and disseminated the risks associated with early failure of the Defective Device, Plaintiff and Plaintiff's surgeon would have avoided the risk of implantation of the Defective Device and/or medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

124. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful conduct in failing to disseminate information related to the early failure of the Defective Device.

125. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FOURTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

126. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

127. Defendants made fraudulent misrepresentations with respect to the Defective Device in the following particulars:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defective Device had been tested and found to be safe and effective for use in TKA, including being safe and effective for use in overweight or obese patients;
- b. Upon information and belief, Defendants represented that the Defective Device was safer than other alternative medical devices; and
- c. Failed to dissemination information on known high early failure rates of the Defective Device.

128. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks associated with implantation of the Defective Device to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

129. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them.

130. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of the Defective Device.

131. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

132. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

133. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

134. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning the Defective Device, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

135. Defendants disseminated to health care professionals and consumers – through published labels, marketing materials, direct communications, and otherwise – information that misrepresented the efficacy and longevity of the Defective Device with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant the Defective Device.

136. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that health care professionals and consumers of the Defective Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Defective Device.

137. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the efficacy and longevity of the Defective Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

138. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that surgeons would implant the Defective Device in reliance on the information disseminated by Defendants, and that the patients implanted with the Defective Device would be placed in peril of suffering early failure and require revision surgery if the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

139. From the time the Defective Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety, efficacy, and longevity of the Defective Device. Defendants made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, including:

- a. Stating that the Defective Device had been tested and found to be safe and effective implant for TKA, including being safe and effective for use in overweight or obese patients;
- b. Concealing, misrepresenting, and actively downplaying the severe and life threatening risks of harm related to the implantation of the Defective Device, when compared to comparable or superior alternative TKA devices; and
- c. Misrepresenting the Defective Device's risk of unreasonable and dangerous early failure.

140. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

141. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

142. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Defective Device.

143. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that the Defective Device had been tested and found to be a safe and effective TKA implant option.

144. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

145. Defendants failed to exercise ordinary care in making their representations concerning the Defective Device and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Defective Device.

146. Defendants engaged in a nationwide marketing campaign, over-promoting the Defective Device in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Defective Device while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to patients implanted with the Defective Device, when compared to comparable or superior alternative TKA implant options. Defendants negligently misrepresented the Defective Device's safety, efficacy, and longevity.

147. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

148. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related

expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SIXTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

149. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

150. Throughout the relevant time period, Defendants knew that the Defective Device was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risk of early failure associated with implantation of the Defective Device.

151. Defendants fraudulently concealed information with respect to the Defective Device in the following particulars:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, direct physician communications, and regulatory submission that the Defective Device was safe and fraudulently withheld and concealed information about the severity of the substantial risks early failure of the Defective Device;

- b. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, direct physician communications, and regulatory submission that the Defective Device was safe and fraudulently withheld and concealed information about the increase risk of failure in overweight and obese patients; and
- c. Upon information and belief, Defendants represented that the Defective Device was safer than other alternative TKA options and fraudulently concealed information which demonstrated that the Defective Device was not safer than alternatives available on the market.

152. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of the Defective Device because:

- a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of implantation of the Defective Device;
- b. Defendants knowingly made false claims and omitted important information about the safety, efficacy, and longevity of the Defective Device in the documents and marketing materials Defendants provided to physicians and the general public; and
- c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of the Defective Device from Plaintiff.

153. As the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, Defendants had unique knowledge and special expertise regarding the Defective Device. This placed them in a position of superiority and influence over Plaintiff and

Plaintiff's healthcare providers. As such, Plaintiff and Plaintiff's health care providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

154. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or be implanted with the Defective Device.

155. The concealment and/or non-disclosure of information by Defendants about the severity of the risks of early failure after implantation of the Defective Device was intentional, and the representations made by Defendants were known by them to be false.

156. The concealment of information and the misrepresentations about the Defective Device were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase the Defective Device and Plaintiff's health care providers would recommend and implant the Defective Device.

157. Plaintiff, Plaintiff's doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk of early failure, including the increased risk of failure in overweight and obese patients, after implantation of the Defective Device.

158. Had Defendants not concealed or suppressed information regarding the severity of the risks of early failure of the Defective Device, Plaintiff's physicians would not have used the Defective Device in Plaintiff's TKA and/or would have medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

159. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's health care professionals from acquiring material information regarding the lack of

safety, efficacy, and longevity of the Defective Device, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

160. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

161. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

162. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing the Defective Device, which is unreasonably dangerous and defective, thereby placing the Defective Device into the stream of commerce.

163. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials

disseminated by Defendants or their authorized agents or sales representatives, that the Defective Device:

- a. was safe and fit for its intended purposes;
- b. was of merchantable quality; and
- c. had been adequately tested and found to be safe and effective for implantation in TKA.

164. These express representations include incomplete marketing materials and labeling that purports, but fails, to include the true risks associated with high early failure rates of the Defective Device. In fact, Defendants knew or should have known of the high early failure rates associated with implantation of the Defective Device including an increased risk of early failure in overweight and obese patients. Despite this, Defendants expressly warranted the Defective Device as safe and effective for implantation in TKA.

165. Defendants advertised, labeled, marketed, and promoted the Defective Device, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce the Defective Device's purchase or implantation, thereby making an express warranty that the Defective Device would conform to the representations. More specifically, the marketing materials and labeling of the Defective Device did not and does not contain adequate information about the true risks of high early failure rate and the injuries complained of herein.

166. Despite this, Defendants expressly represented that the Defective Device was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective for implantation in TKA including warranting the Defective Device was safe and effective for use in overweight and obese patients.

167. The representations about the Defective Device contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

168. The Defective Device does not conform to Defendants' express representations because it is not safe, effective, or have the implantation life warranted by Defendants. Therefore, Defendants breached the aforementioned warranties.

169. At all times relevant, the Defective Device did not perform as safely and as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

170. Neither Plaintiff nor Plaintiff's surgeon had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Defective Device.

171. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when recommending and implanting the Defective Device.

172. Had the marketing and labeling information for the Defective Device accurately set forth the true risks associated with the high early failure rate and increased risk of failure of the Defective Device in overweight and obese patients and potential injuries, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended purpose, Plaintiff could have avoided the injuries complained of herein.

173. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other

related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

174. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

175. Defendants manufactured, distributed, advertised, promoted, and sold the Defective Device.

176. At all relevant times, Defendants knew of the purpose for which the Defective Device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

177. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device during TKA.

178. The Defective Device was neither safe for its intended purpose nor of merchantable quality, as impliedly warranted by Defendants, in that the Defective Device has dangerous propensities when used as intended and can cause serious injuries, including early

failure resulting in additional painful revision surgeries and the risks associated with additional surgery.

179. At all relevant times, Defendants intended that the Defective Device be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such purpose, despite the fact that the Defective Device was not adequately tested.

180. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device as marketed by Defendants. As such, Plaintiff was a foreseeable user of the Defective Device.

181. Upon information and belief, Plaintiff and/or Plaintiff's health care professionals were at all relevant times in privity with Defendants.

182. The Defective Device was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

183. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell the Defective Device only if it was indeed of merchantable quality and safe and fit for its intended purpose.

184. Defendants breached their implied warranty to consumers, including Plaintiff. The Defective Device was not of merchantable quality, nor was it safe and fit for its intended purpose.

185. Plaintiff and Plaintiffs physicians reasonably relied upon Defendants' implied warranty for the Defective Device when recommending and implanting the Defective Device.

186. Plaintiff's use of the Defective Device was as intended and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

187. The Defective Device was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

188. Defendants breached the warranties of merchantability and fitness for its particular purpose because the Defective Device was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

189. The harm caused by the Defective Device far outweighed its alleged benefit, rendering the Defective Device more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

190. Neither Plaintiff nor Plaintiff's health care professionals reasonably could have discovered or known of the risk of early failure associated with the Defective Device.

191. Defendants' breach of these implied warranties caused Plaintiff's injuries.

192. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

NINTH CAUSE OF ACTION
FRAUD

193. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs excluding the previously named first and second causes of action, with the same force and effect as if more fully set forth herein.

194. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, Plaintiff's health care professionals, the health care industry and consumers that the Defective Device had been adequately tested in clinical trials and was found to be safe and effective for implantation in TKA.

195. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risks associated with the implantation of the Defective Device. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of the Defective Device, such as Plaintiff.

196. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and Plaintiff's health care professionals, so as to induce them to recommend, purchase, and implant the Defective Device, despite the risk of severe life threatening injuries, which Defendants knew were caused by the product.

197. The Defendants fraudulently and intentionally concealed material information, as aforesaid, Defendants knew that the Defective Device was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the Defective Device's risk.

198. Defendants fraudulently and intentionally failed to disclose and warn of the high early failure rate and associated injuries described herein, which were known by Defendants to result from implantation of the Defective Device.

199. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with implantation of the Defective Device from physicians and patients, including Plaintiff and Plaintiff's surgeon, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy, safety, and longevity of the Defective Device. For example:

- a. The Defective Device was not as safe and effective as other TKA implants given its intended purpose;
- b. Defendant's did not inform patients or healthcare providers that Defendants knew as early as 2008 that the Defective Device posed an increased risk of injury to overweight and obese patients;
- c. The Defective Device is not a safer and more effective method for TKA procedures than other available treatments;
- d. The risks of early failure associated with the implantation of the Defective Device was greater than the risks of early failure associated with other TKA implants;
- e. The risk of early failure with the Defective Device was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;
- f. The increased risk of early failure with the Defective Device when implanted in overweight and obese patients was known by Defendants, but Defendants

knowingly failed to adequately notify patients and healthcare providers of the increased risk;

- g. The increased risk of early failure with the Defective Device when implanted in overweight and obese patients was known by Defendants, but Defendants knowingly made material misrepresentations and omissions of fact on which Plaintiff and Plaintiff's surgeon relied;
- h. Defendants knew that the risk of early failure associated with the implantation of the Defective Device was greater than the risks of harm associated with other TKA implants, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff and Plaintiff's surgeon relied;
- i. Defendants continued to manufacture, sale, distribute, and market the Defective Device as safe and effective for all patients even after obtaining knowledge that the Defective Device posed an increased risk of failure and injury to overweight and obese patients;
- j. The limited clinical testing revealed that the Defective Device had an unreasonably high early failure rate, above and beyond those associated with other TKA implants;
- k. Defendants intentionally and knowingly failed to disclose and concealed the early failure rate discovered in any clinical studies and trial results;
- l. Defendants had knowledge of the dangers involved with the implantation of the Defective Device, which dangers were greater than those associated with other TKA implants;

- m. Defendants intentionally and knowingly failed to disclose that patients using the Defective Device could suffer early failure and additional surgeries at a greater rate of occurrence than other, similar, TKA implants; and/or
- n. The Defective Device was defective, and had an unreasonably high risk of early failure and associated injuries, including the specific injuries described herein.

200. Defendants had access to material facts concerning the defective nature of the Defective Device and its propensity to result in early failure and cause serious and dangerous injuries and damages to persons who are implanted with the Defective Device and suffer additional surgeries, including revision surgery, information that was not publicly disseminated or made available, but instead was actively suppressed by Defendants.

201. Defendants' intentional concealment and omissions of material fact concerning the safety of the Defective Device was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's surgeon to purchase, recommend, and/or implant the Defective Device, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that the Defective Device was a safe and effective medical device.

202. At the time Plaintiff purchased and was implanted with the Defective Device, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute a true, complete, and accurate portrayal of the Defective Device's safety, efficacy, and longevity.

203. Defendants knew and had reason to know that Defective Device could and would cause serious personal injury to the users of the product, and that the product was inherently dangerous in a manner that exceeded any purported disclosures given by Defendants.

204. Defendants knew and had reason to know that Defective Device posed an increased risk of failure when implanted in overweight and obese patients, and that the product was inherently dangerous in a manner that exceeded any purported disclosures given by Defendants.

205. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to be implanted with, and in fact was implanted with, the Defective Device during a TKA, thereby sustaining injuries and damages, including additional surgery and associated injuries. Defendants knew and had reason to know that Plaintiff and Plaintiff's health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and Plaintiff's health care professionals would not have recommended and implanted the Defective Device if the true facts regarding the Defective Device had not been concealed by Defendants. Additionally, Plaintiff and Plaintiff's health care professionals would have medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device

206. During the marketing and promotion of the Defective Device to health care professionals, neither Defendants nor the co-promoters who were dealing the Defective Device on Defendants' behalf, warned health care professionals, including Plaintiff's surgeon, that the Defective Device had a high early failure rate.

207. During the marketing and promotion of the Defective Device to health care professionals, neither Defendants nor the co-promoters who were dealing the Defective Device on Defendants' behalf, warned health care professionals, including Plaintiff's surgeon, that the

Defective Device posed an increased risk of early failure and serious injury in overweight and obese patients.

208. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was crucial to understanding the true dangers inherent in the implantation of the Defective Device.

209. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that the Defective Device was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of any of Defendants' clinical tests and research.

210. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and patients implanted with the Defective Device, including Plaintiff. Defendants knew of the Defective Device's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

211. As foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a painful knee revision surgery and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper, Plaintiff also demands that the issues contained herein be tried by a jury.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

- a) For general damages in a sum in excess of the jurisdictional minimum of this Court;
- b) For medical, incidental and hospital expenses according to proof;
- c) For pre-judgment and post-judgment interest as provided by law;
- d) For consequential damages in excess of the jurisdictional minimum of this Court;
- e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;
- g) For attorneys' fees, expenses and costs of this action; and
- h) For such further and other relief as this Court deems necessary, just and proper.

Dated: October 11, 2017

/s/ Jon C. Conlin
Jon C. Conlin
Elizabeth E. Chambers

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